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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,368	08/06/2003	Kenneth Stewart	6714-46501	6917

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BARNES & THORNBURG LLP
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EXAMINER

NELSON, CHRISTINE L

ART UNIT	PAPER NUMBER
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3775

NOTIFICATION DATE	DELIVERY MODE
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02/08/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/634,368	Applicant(s) STEWART, KENNETH	
	Examiner JAMES L. SWIGER	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-45 is/are pending in the application.
- 4a) Of the above claim(s) 35 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23,29-31,36 and 38-45 is/are rejected.
- 7) ☒ Claim(s) 24-28 and 32-34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/10/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species:

- a) Fig. 1
- b) Fig. 2
- c) Fig. 3a and 3b
- d) Fig. 4
- e) Fig. 5

Upon the allowance of a generic claim, applicant will be entitled to the consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species (MPEP 809.02(a)).

During a telephone conversation with Ms. Evelyn Sommer on 5/10/2006, a provisional election was made without traverse to prosecute **species D (Fig. 4)** (*from office action dated 5/16/2006*).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23 and rejected under 35 U.S.C. 102(b) as being anticipated by Watanabe (US patent 5,265,278). Watanabe discloses a hollow cap (1) and a fastener portion (10). With regards to functional language it is noted that the cover and fastener of Watanabe, appropriately sized and shaped would be fully capable of performing the functions of creating a medically safe barrier that is impermeable and that would protect the bone instrumentation from tissue growth. Further, the fastener portion would be fully capable of securing the cap around bone instrumentation.

Claims 23, 29, 38, 30-31, 39 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellman (US patent 4,428,375). Ellman discloses bone instrumentation cover device (Figs. 1-4) comprising a hollow cap (15) made of a medically safe material such as Dacron (Col. 2, lines 30-40) that is capable of removal in a subsequent procedure, and a fastener portion such as adjustable, multiple sutures (21/22) connected to the lower portion of the cap, and wherein the sutures (21/22) may also be considered non-adjustable (or may be cut) that function to tighten the lower end of the cap onto a fastener. Ellman further discloses that the cap has solid parts (16). The sutures or strings may also be resorbable (Col. 2, lines 30-45). It is noted that the cap would be fully capable of covering substantially all of the bone instrumentation material.

It is noted that Ellman is fully capable of being a “medically safe physical barrier.” As noted above, Ellman is made of a medically safe material. However, it is noted that even though Ellman is designed as a mesh, and the examiner acknowledges that the mesh may not be a *complete, impenetrable* barrier, the mesh is at least fully capable of providing a protective, physical barrier between the bone elements and tissue. If the mesh is less stretched out, it would provide more of a barrier. Defining the mesh as a physical barrier is similar to a wire fence separating a back yard from the surrounding property--it provides a physical barrier even if it is not solid like a wooden fence. In terms of biological tissue, a solid tissue such as a muscle plane may be prevented from complete growth around the bone anchor.

Applicant is also reminded that with regard the statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Ellman which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claims 40-43 are rejected under 35 U.S.C. 102(e) as being anticipated Barron et al. (hereafter “Barron”) by US Publication 2003/0163161.

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Barron discloses a bone instrumentation protective cover, or barrier material, for isolating bone implants that are installed in the body. Barron discloses various materials that may be used as a protective barrier (see pars 0014 and 0015) as well as a hydrogel (see claim 5). The bone implants may be pedicle screws such as the screw-in type that goes into bone (par 0030) and where the protective material is fully capable of protecting the bone anchors from ingrowth and may also prevent abrasion of the patient's tissue on the bone anchor (see Abstract). The barrier is fully capable of fitting over the instrumentation, as has the ability to isolate bone anchors (see Abstract) and also is ellipsoidal (see par 0013).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellman '375 in view of Barron. Ellman discloses the claimed invention except for wherein the hollow cap comprises a hydrogel. Barron discloses that a hydrogel may be used to protect and surround bone implants or instrumentation (see notations above). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Ellman having at least a hollow cap comprising a

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hydrogel in view of Barron so that the barrier can better protect the instrumentation by being biocompatible as well as absorbing body fluid in the surgical area.

Response to Amendment

The affidavit under 37 CFR 1.132 filed 12/11/2009 IS SUFFICIENT to overcome the rejection of claims 24-28 and 32-34 based upon Ellman as set forth in the last Office action because: Ellman does not have a separate cinch ring from the hollow cap that is tubular to which the suture strings can be used to tighten the cap onto the bone fasteners.

However the affidavit is NOT sufficient in overcoming all arguments with respect to Ellman. See rejections found above.

Allowable Subject Matter

Claims 24-28 and 32-34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Supplemental Amendment

On January 26, 2010, applicant submitted a supplemental amendment in response to the previously submitted amendment filed on 12/11/2009.

It is noted that the amendment filed on 1/26/2010 is HEREBY ENTERED.

Response to Arguments

Applicant's arguments filed 1/26/2010 have been fully considered but they are not persuasive. Examiner respectfully disagrees with applicant in regards to the

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medically safe barrier between at least part of the bone anchor/instrumentation and surrounding tissue. Revised rejections are discussed above. Additionally, other prior art still reads on the claimed invention. Certain claims have been indicated as allowable. Applicant has expressed interest in possibly pursuing the current claims on appeal. However, the examiner advises applicant to consider the allowable subject matter to expedite prosecution.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER whose telephone number is (571)272-5557. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L. SWIGER/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
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